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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/669,051 09/24/00 FRANANO

N 55225

EXAMINER

HM12/0921
DIKE, BRONSTEIN, ROBERTS & CUSHMAN
INTELLECTUAL PROPERTY PRACTICE GROUP
P.O. BOX 9169
EDWARDS & ANGELL
BOSTON MA 02209

SRIVASTAVA, K

ART UNIT

PAPER NUMBER

1651

DATE MAILED:

09/21/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/669,051

Applicant(s)

FRANANO, NICOLAS F.

Examiner

Dr. Kailash C. Srivastava

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 24 September 2000.
- 2a) ☐ This action is FINAL.
- 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

DETAILED ACTION

1. Claims 1 - 39 are pending.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I - Claims 1-12 drawn to a method to treat obstructed biological conduit,
Classified under Class 424, Subclass 94.64.

Group II - Claims 13-18 drawn to a method to dilate a biological conduit comprising
administering a therapeutic agent to the said biological conduit, Classified
under Class 514, Subclass 929.

Group III - Claims 19-24 drawn to a Pharmaceutical Kit, Classified under Class 422,
subclass 230+.

Group IV - Claims 25-35 drawn to a method to treat a mammal suffering from or
susceptible to an obstructed biological conduit, classified under Class 424,
Subclass 94.6.

Group V- Claims 36--39 drawn to a method to treat a mammal suffering from or
susceptible to an obstructed biological conduit with a composition
comprising an agent that solubilizes collagen or elastin, classified under
Class 424, Subclass 94.2.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions in Groups I-II and IV-V are unrelated processes. Inventions are
unrelated if it can be shown that they are not disclosed as capable of use together and they
have different modes of operation, different functions, or different effects (MPEP § 806.04,
MPEP § 808.01). In the instant case, invention of Group I is a method to de-obstruct a
biological conduit, whereas invention in Group V is drawn to a method to treat a mammal

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suffering from obstructed biological conduit by administering to the said mammal a composition that solubilizes collagen or elastin. Similarly, in method of Group II, the biological conduit is dilated with a therapeutic agent, but invention of Group IV is to treat the mammal by degrading "extracellular matrix of tissue of the conduit obstruction". Thus, anyone of these inventions (e.g., dilation of obstructed conduit vs. treatment to degrade elastin) will not be practiced simultaneously and therefore, the inventions clearly have different modes of operation, functions and effects.

Invention in Group III is related to inventions in Groups I-II and IV-V as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the obstructed biological conduit may also be de-obstructed by surgical means. Similarly, the enzyme mixture may also be applicable in food processing industry to prepare comminuted meat products.

Because these **inventions are distinct for the reasons given above** and have acquired a **separate status in the art as shown by their different sub-classes**, and their recognized **diverse subject matter**, restriction for examination purposes **as indicated is proper**.

4. This application contains claims directed to compositions comprised of a variety of ingredients.

Even though each of the above inventions relates to the same Class, the search for each of the above inventions is not co-extensive, particularly with regard to the literature search. This is because of the fact that the inventive groups discussed above incorporate numerous ingredients within each of the same, single composition. For example, to conduct a literature search for invention in Group IV that is constituted of different ingredients. To conduct a search in this group for obstruction of different biological conduits alone, one would be searching for a total number of combinations that will be a factorial of 6. Add to that two different products (elastin, collagen), three enzymes or combinations thereof three different categories of blockages and six sub-categories of blockages, the total number

of combinations become minimum of combinations that would be a factorial of 15 with each one of the ingredients up to ingredient number 1 (i.e. 15×14 , 14×13 , 14×12 , 14×11 , ---- 14×1). Thus, this group alone will exert an enormous search burden on the Examiner. Therefore, if the applicant elects Group **I, IV or V above**, **the applicant must also make election of species by electing a single species** from each of the following categories:

- One of the six conduits among those claimed in Claims 11 and 33.
- One material between collagen and elastin claimed in claims 2, 13, 20-21, 28 and 36-37.
- One of the three enzymes claimed in Claims 8, 22, 29 and 38.
- One of the three categories (stenosis, stricture or lesion) of conditions claimed in Claims 10 and 32.
- One of the four sub-conditions benign biliary stricture, stenosis of hemodialysis graft, intimal hyperplasia, or coronary obstruction) claimed in Claims 34 and 36.

Claims 1, 13, 19, 25 and 36 are generic.

Applicant is advised that a reply to this requirement **must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon**, including any claims subsequently added. An argument that a claim is **allowable or that all claims are generic is considered non-responsive** unless accompanied by an election. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species [MPEP § 809.02(a)].

Should applicant traverse on the ground that the **species are not patentably distinct**, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In

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either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b). Any amendment of inventorship must be **accompanied by a petition under 37 CFR 1.48(b) and by the fee** required under 37 CFR 1.17(I).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (703) 605-1196. The examiner can normally be reached on Monday to Thursday and every other Friday from 8:00 AM to 5:30 P.M (Eastern Daylight Saving, or Standard time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Kailash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1651
(703) 605-1196

KCS
September 13, 2001


LEON B. LANKFORD, JR.
PRIMARY EXAMINER